SUMMARY OF THE QUALITY SYSTEMS COMMITTEE TELECONFERENCE DECEMBER 7, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on December 7, 1999, at 11 a.m. Eastern Standard Time (EST). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (USEPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The list of parking lot issues includes 5 items from NELAC V (Attachment C). Attachment D is a listing of frequently asked questions. Attachment E presents the QS Committee approach to handling comments, comment acknowledgment form letter, guiding principles for reviewing comments and the standard, and commenter template. Attachment F is the updated table that logs and documents the status of comments received by the QS Committee. The QS committee's resolution of comments 3,4,9,12, and 15 listed in the log and status table (Attachment F) are documented in Attachments G, H, I, J, and K, respectively. *The purpose of the meeting was to discuss the resolution of comments received by the QS Committee and any final issues concerning NELAC Vi.*

ACTION ITEMS FROM PREVIOUS MEETINGS

Radiochemical Testing Session

The chair is making arrangements so that Mr. Donivan Porterfield, an expert on radiochemical testing, can provide input/information during the December 14, 1999 3:30-4:30 p.m. session. Mr. Porterfield is a former member of the QS committee and has been invited to provide his expertise during the session.

Homework

This meeting focused on addressing the remaining comments that had been submitted since the July 1999 meeting. The goal of the meeting was to address all the comments prior to the NELAC interim meeting next week. The changes that were discussed in this meeting will be included in the proposed changes distributed at the interim meeting.

Item 8 from the Lehigh Co. Authority

More time will be required to address this item.

Item 9 from West Coast Analytical Service, Inc. (See Attachment I)

- Comment 1. Section 5.6.2. The group discussed potential sources on ethics. Two sources were suggested, a paper by Ann Rosecrance and the website of the American Council for Independent Labs.

Rosecrance, Ann. 1999. On track to quality in the laboratory: The role of an ethics program and data quality review procedure. Environmental Testing and Analysis 8:26-37.

http://www.acil.org/

- Comment 2. Section 5.6.2.c.4.v. The wording in this section has been reviewed a number of times. The group agreed to leave this issue open and consider rewriting the sentence to remove the term "statistically indistinguishable."
- Comment 3. Section 5.9.4.1. Leave as is because the standard means every day of use, not of everyday.
- Comment 4. Section 5.9.4.2. No change.
- Comment 5. Section 5.11.3. No change is proposed. The laboratory must document actual practice including if the temperature is not checked. There are non-invasive measures to check temperature.
- Comment 6. Section 5.12. No change. If the media is kept, the laboratory needs to maintain the means to "read" it.
- Comment 7. Section 5.12.2.b. The wording was revised to clarify the last phrase. The revised wording was submitted for the interim meeting.
- Comment 8. Section 5.12.4.5. No change. Disposal means when the sample is taken out of the normal flow of samples.
- Comment 9. Section 5.13.2.h (probable, but reference unknown). Clarify intent by adding "records of."
- Comment 10. Section 5.13. No change.

Item 10 from Catalyst

These comments will be addressed when the lead respondent is present.

Item 12 from CA ELAP (See Attachment J)

Because these comments were addressed previously, they were not discussed in this meeting. However, the comments and resolution are included in Attachment J.

Item 15 from WI DNR (See Attachment K)

- Comment 1. Section 5.9.4.2. No change as the note was included as a strong introductory point.
- Comment 2. Section 5.9.4.2.1a. No change. Although it was recognized that the commenter wanted specifics in the SOP, the elements of this comment have been addressed elsewhere in the chapter.

- Comment 3 Section 5.9.4.2.1 (e) No change. This section has been reviewed extensively before.
- Comment 4. Section 5.9.4.2.1 (I) No change as a laboratory must have an SOP.
- Comment 5. Section 5.9.4.2.2 (a) No change.
- Comment 6. Section 5.9.4.2.2 (b) No change as continuing calibration must be performed as long as it is the established procedure.
- Comment 7. Section 5.9.4.2.2 (d) No change.

Item 4 from South Carolina (see Attachment H)

The following comments require no change and were not discussed: Comment 3, 6, 7, 8, 11-13, 14, 15, 16 , 18, 19, 20.

- Comment 1. Introduction was discussed in the meeting and the committee agreed to no change.
- Comment 2. Introduction. The committee agreed to the proposed wording change.
- Comment 4. Section 5. The committee agreed that the term "environmental tests" did not need to be changed, but in discussing this issue the committee agreed to alternative language for the sentence: " This standard sets out the general requirements that a laboratory has to successfully demonstrate to be recognized as competent to carry out specific environmental tests."
- Comment 5. Section 5.1.b The committee agreed to no change.
- Comment 9. Section 5.4.2.b The committee agreed to maintain the ISO language.
- Comment 16. Section 5.5.4 The committee agreed to delete "adequate" in 1 and 2 and "sufficient" in 3.
- Comment 17. Section 5.6 The committee agreed to maintain the ISO language.
- Comment 21. Section 5.8 The committee agreed to delete "when appropriate" from 5.8.d. "Otherwise appropriate" includes using instrument logs or other records.
- Comment 22. Section 5.9.4.2.b This was discussed previously.

Attachment H indicates that the meeting closed at this point in the discussion. The remaining comments will be discussed at a future meeting.

CONCLUSION

The committee agreed to submit their changes to the chair after the Fifth NELAC Interim Meeting.

QS TELECONFERENCE SCHEDULE

There are no additional QS Committee teleconferences scheduled before NELAC Vi, which will be held Dec 14-16, 1999 in Washington, DC.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
NOVEMBER 23, 1999

Item No.	Action Item	Date to be Completed
1.	QS Committee members will submit comment responses to be included in the minutes: Mr. Slayton (comments 3 and 4), Mr. Nielsen (comment 15), Mr. Mendenhall (comment 9), and Mr. Delisle (comment 12).	December 10, 1999
2.	Mr. Slayton will update the comment "homework" table.	December 10, 1999
3.	Ms. Boshes and Mr. Beard will prepare the draft minutes of the teleconference.	After comment responses are received.
4.	NELAC Vi is scheduled for December 14-16.	N/A

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
DECEMBER 7, 1999

Name	Affiliation	Phone Numbers
Mr. Joe Slayton	USEPA, Region III, OASQA	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
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Ms. Sylvia S. Labie (absent)	Florida Department of Environmental Protection	T: 850-488-2796 F: 850-922-4614 E: labie_s@dep.state.fl.us
Mr. David Mendenhall	Utah Department of Health	T: 801-584-8470 F: 801-584-8501 E: dmendenh@doh.state.ut.us
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Mr. Scott D. Siders (absent)	Illinois Environmental Protection Agency	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
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Attachment C

PARKING LOT ITEMS/ISSUES
QUALITY SYSTEMS COMMITTEE

Items/issues will remain in the Parking Lot until they are completed.

The following items were added to the parking lot following the November 24, 1999 meeting:

1. Review terms in Chapter 5 for terms needing clarification, e.g., “such as,” “independent standard,” “alternate source,” “second” or “alternate source.”

2. Combine “Analyst Training” and “Verification” into same section.

3. ~~Clarify “Custody” versus “Sample Tracking.”~~ Done

4. ~~Finalize Radiochemistry section~~. Done

5. ~~Come to closure on Air Testing issues.~~ Done

Attachment D

FREQUENTLY ASKED QUESTIONS
QUALITY SYSTEMS COMMITTEE
DECEMBER 7, 1999

Some Frequently Asked Questions Concerning NELAC QS (Chapter 5):

1. Question: If a mandated method (required by EPA or State Authority) is less stringent than the QS standards what do I follow?

Answer: The most restrictive/demanding.

2. Question: Do the QS standards require the use of any specific method?

Answer: No, QS does not require the use of a specific method/s. Chapter 5 allows the user to select an appropriate method. However, regulatory agencies may mandate the use of a specific method (See also Question 3).

3. Question: Do the QS standards allow for the use of the PBMS approach?

Answer: Yes. However, the QS standards may include additional QS checks/requirements (considered by NELAC to be essential) than those associated with a PBMS method for a given project. Such additional requirements would also apply to conventional or non-PBMS methods as well.

4. Question: Do the QS standards apply to small laboratories?

Answer: Yes. The standards include essential QC procedures and are applicable to environmental laboratories regardless of size and complexity. It is suggested that the amount of effort that will be required to attain the standards will be dependent on whether the laboratory already is operating under a quality system (with established and documented SOPs and QC procedures) more then upon the size of the laboratory.

5. Question: If my laboratory is measuring high level concentrations and is set-up (perhaps even optimized) to analyze at such levels and is only interested in whether a high level regulatory limit is exceeded, why do I have to determine a detection limit?

Answer: A detection limit is considered essential to verify (confirm and document) that the laboratory is actually able to detect and measure at the regulatory or decision limit. Detection limit determinations are also considered an important consideration with regard to the quantitation range selection particularly with regard to the choice of the concentration of the lowest calibration standard. Changes to the standard will be proposed at the January 1999 Interim Meeting, which no longer specify that the MDL (40 CFR Part 136) procedure be employed, unless it is mandated by the test method or applicable regulation. In the proposed revision, the term "detection limit" may not be the lowest concentration level attainable by a given analytical method, but rather that

it is a concentration that is actually measurable (and verified) using the procedures, e.g., equipment, analytical method, routinely employed for sample analyses (could be relatively high concentration). The detection level should be appropriate or relevant for the intended use of the data. In some cases this will of necessity be the lowest concentration level attainable, e.g., low level drinking water or wastewater permit limits.

6. Question: Why are we revisiting the calibration and detection parts of the standards?

Answer: At NELAC IV the Quality Systems Committee received numerous comments that the calibration and detection parts of the standards were too prescriptive and were not consistent with a PBMS environment. The Committee has attempted to propose changes to the calibration and detection parts of the standards that provide essential elements for those two quality system standards and that will support the anticipated needs of PBMS. The Committee believes the proposed language is less prescriptive (i.e., more flexibility), yet hopefully still ensures the quality of the analytical data.

In making these proposed changes the Committee has attempted to balance the need for more flexibility in the standards with the desire to not go to far and introduce excessive flexibility that could prove to be too vague or ill-advised. The Committee is currently discussing and considering its proposed language and public comments on the proposed language changes. The Committee is committed to assuring that the NELAC Quality Systems standards provide a foundation for PBMS implementation.

7. Question: Several States have indicated that it is very desirable that a laboratory already be actively analyzing samples for a particular program and by a method for which they want to be accredited. However, these same states have relayed that this ideal scenario is often not the case, as a laboratory may request accreditation in attempts to expand their scope of analytical services or in order to satisfy contractual requirements. These states ask: How will the QS standards help ensure that laboratories will have sufficient data for an onsite assessment especially given the proposed changes to the MDL section?

Answer: The MDL, section D.1.4, in the 1998 NELAC standards has a requirement that "MDLs" be determined initially (40 CFR Part 136, Appendix B) and be verified yearly by the analysis of at least one clean matrix sample spiked at the current reported MDL. Under the proposed revision to Section D.1.4, "Detection Limits" are to be determined initially and each time there is significant change in the test method or instrument type. The proposed standard still requires "MDL" if required in the mandated test method or applicable regulation. If the MDL is not required a "detection limit" must still be determined. Therefor the new section D.1.4 requirements should still help assure that performance data will be available for review by inspectors . In addition, laboratories are required to successfully complete two out of three PT samples yearly and this data would be available for review, as per section 5.5.4 and Chapter 2) . However, under the current PT requirements this may only include one method of multiple methods employed by a laboratory for a given parameter group, e.g., metals.

Laboratories also must perform an Initial Demonstration of Analytical Capability (5.10.2.1, D.1.3 Method Evaluation and Appendix C) . This data would be available for on-site review. Also note that the QS committee plans to expand Appendix C (IDC) procedures prior to NELAC V to make it applicable to methods for which spiking is difficult or impossible, e.g., Total Suspended Solids, which should further ensure that performance data is available for review.

In addition under Section 5.6.2.3.c. of QS, the Laboratory Management must ensure that the training of personnel is kept up-to-date, which includes a analyst certification to perform the most recent version of the test method (the approved method or standard operating procedure) and documentation of continued proficiency by at least one of the following once per year: I. acceptable performance of a blind sample (single blind to the analyst); ii. another initial demonstration of method capability; iii. successful analysis of a blind performance sample on a similar test method using the same technology; iv. at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; vi if I-iv cannot be performed, analysis of authentic samples that have been analyzed by another trained analyst with statistically indistinguishable. These requirements should further help assure performance data is available on-site for review.

GUIDING PRINCIPLES/REVIEW CRITERIA **Attachment D**

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Attachment E

ACKNOWLEDGMENT LETTER, REVIEW GUIDELINES, and COMMENTER TEMPLATE
Quality Systems Committee
December 7, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first come basis. We have placed a template (topic listing) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,

Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following topic listing:

Comment ID #: Date:

Commenter's Name:
Affiliation:

Email Address:

Committee Lead on Response (Name):
:::
::::::
Comment #1: Standard Rev. # , SECTION#

TO BE COMPLETED BY THE COMMENTER:

A: Current Standard Text

B: COMMENT with Rationale

C: Proposed Wording Change

TO BE COMPLETED BY THE COMMITTEE:

D: OUTCOME (Including any proposed change)

E: RATIONALE

Comment #2: Standard Rev. #, SECTION#

TO BE COMPLETED BY THE COMMENTER:

A: Current Standard Text

B: COMMENT with Rationale

C: Proposed Wording Change

TO BE COMPLETED BY THE COMMITTEE:

D: OUTCOME (Including any proposed change)

E: RATIONALE